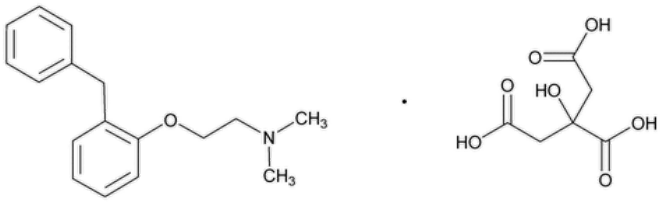
Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-A31D4B9F-6F35-4BE3-90CD-FB98FC51E49D_4_en-US
DOI: https://doi.org/10.31003/USPNF_M64390_04_01
DOI Ref: c7m0m



# Phenyltoloxamine Citrate



$C_{17}H_{21}NO \cdot C_6H_8O_7$ 447.48

*N*,*N*-Dimethyl-2-(α-phenyl-*o*-tolyloxy)ethylamine, citrate (1:1) salt.

2-(2-Dimethylaminoethoxy)diphenylmethane, citrate (1:1) salt

Phenyltoloxamine dihydrogen citrate CAS RN®: 1176-08-5; UNII: 8UE48MJH8M.

» Phenyltoloxamine Citrate contains not less than 99.0 percent and not more than 101.0 percent of $C_{17}H_{21}NO \cdot C_6H_8O_7$, calculated on the dried basis.

**Packaging and storage**—Preserve in well-closed containers. Store at room temperature.

**USP Reference standards** ⟨11⟩—

USP Phenyltoloxamine Citrate RS

USP Phenyltoloxamine Related Compound A RS

2-(2-Benzylphenoxy)ethylmethylamine hydrochloride.

$C_{16}H_{19}NO \cdot HCl$ 277.79

***Change to read:***

**Identification,** ▲*Spectroscopic Identification Tests* ⟨197⟩*, Infrared Spectroscopy: 197K*▲ (CN 1-May-2020) ·

**Melting range,** *Class 1a* ⟨741⟩**:** between 137° and 143°.

**pH** ⟨791⟩**:** between 3.2 and 4.2, in a solution (1 in 100).

**Loss on drying** ⟨731⟩—Dry it in vacuum at 80° for 3 hours: it loses not more than 0.5% of its weight.

**Residue on ignition** ⟨281⟩**:** not more than 0.1%.

**Related compounds**—

*Resolution solution*—In a separatory funnel dissolve about 10 mg each of USP Phenyltoloxamine Citrate RS and USP Phenyltoloxamine Related Compound A RS, accurately weighed, in 50 mL of water. Add 5 mL of ammonium hydroxide, and extract with three 10-mL portions of methylene chloride. Combine the extracts, dry the solution over anhydrous sodium sulfate, and gently evaporate to dryness. Dissolve the residue in 20 mL of methylene chloride.

*Test solution*—In a separatory funnel dissolve about 400 mg of Phenyltoloxamine Citrate, accurately weighed, in 50 mL of water. Proceed as directed for *Resolution solution,* beginning with "Add 5 mL of ammonium hydroxide."

*Chromatographic system* (see *Chromatography* ⟨621⟩)—The gas chromatograph is equipped with a split injection system, a flame-ionization detector, and a 0.32-mm × 25-m column coated with a 0.45-µm film of phase G27. The carrier gas is helium, flowing at a rate of about 29 cm per second, with a split flow rate of about 25 mL per minute. The column temperature is programmed as follows. Initially the temperature of the column is equilibrated at 190° for 3 minutes, then the temperature is increased at a rate of 4° per minute to 240°, and maintained at 240° for 8 minutes. The injection port and the detector temperatures are maintained at 280°. Chromatograph the *Resolution solution,* and record the peak responses as directed for *Procedure:* the resolution, *R*, between phenyltoloxamine and phenyltoloxamine related compound A is not less than 1.5.

*Procedure*—Inject a volume (about 1 µL) of the *Test solution* into the chromatograph, record the chromatograms, and measure the peak responses. Calculate the percentage of each impurity in the portion of Phenyltoloxamine Citrate taken by the formula:

$$100(r_i/r_s)$$

in which $r_i$ is the peak response of each impurity; and $r_s$ is the sum of the responses of all the peaks, excluding the solvent peaks: not more

than 0.2% of phenyltoloxamine related compound A; not more than 0.1% of any other individual impurity; and not more than 1.0% of total impurities is found.

**Assay**—Dissolve about 0.5 g of Phenyltoloxamine Citrate, accurately weighed, in 80 mL of glacial acetic acid, and titrate with 0.1 N perchloric acid VS, determining the endpoint potentiometrically. Perform a blank determination, and make any necessary correction (see *Titrimetry* ⟨541⟩). Each mL of 0.1 N perchloric acid is equivalent to 44.75 mg of $C_{17}H_{21}NO \cdot C_6H_8O_7$.

**Auxiliary Information** - Please check for your question in the FAQs before contacting USP.

| Topic/Question | Contact | Expert Committee |
|---|---|---|
| PHENYLTOLOXAMINE CITRATE | Documentary Standards Support | SM52020 Small Molecules 5 |
| REFERENCE STANDARD SUPPORT | RS Technical Services<br>RSTECH@usp.org | SM52020 Small Molecules 5 |

**Chromatographic Database Information:** Chromatographic Database

**Most Recently Appeared In:**
Pharmacopeial Forum: Volume No. PF 30(4)

**Current DocID: GUID-A31D4B9F-6F35-4BE3-90CD-FB98FC51E49D_4_en-US**
**DOI: https://doi.org/10.31003/USPNF_M64390_04_01**
**DOI ref: c7m0m**